

**REMARKS**

Claims 1, 4-48, and 51-84 are pending in this application. Claims 24-47 are withdrawn from consideration as being drawn to non-elected claims.

Applicants expressly reserve the right to pursue prosecution of any excluded subject matter or claim embodiments in one or more future continuation and/or divisional application(s).

**Rejection Under Provisional Obviousness-Type Double Patenting**

Claims 1, 4-2, 48 and 51-84 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-15, 18-22, 27-29 and 51-62 of co-pending Application 10/214,799. This is a provisional obviousness-type double patenting rejection and there are no issued claims. Applicants will address this provisional rejection when there is otherwise allowable subject matter.

**Rejection under 35 U.S.C. §102**

I. Claims 1, 4-23, 48, and 51-84 are rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Schwartz et al. (WO 98/55495) (“Schwartz”). Applicants respectfully traverse this rejection.

For a claim to be anticipated by a reference, the reference must teach each and every element of the claim. Claim 1 recites an immunomodulatory polynucleotide/ microcarrier (IMP/MC) complex, comprising: a polynucleotide covalently linked to the surface of a biodegradable micro carrier (MC), wherein said polynucleotide comprises the sequence 5'-CG-3', wherein the polynucleotide is greater than 6 nucleotides in length and wherein said MC is less than 10 µm in size. Claim 48 recites a kit, comprising: an immunomodulatory polynucleotide/microcarrier (IMP/MC) complex, said complex comprising a polynucleotide covalently linked to the surface of a biodegradable microcarrier (MC), wherein said polynucleotide comprises the sequence 5'-CG-3', wherein the polynucleotide is greater than 6 nucleotides in length and wherein said MC is less than 10 µm in size; and instructions for use of the IMP/MC complex in

immunomodulation of an individual. Claim 70 recites, in part, a kit comprising an (IMP/MC) wherein the polynucleotide is 7 nucleotides in length.

While Schwartz describes various combinations of immunostimulatory polynucleotides with other components, Applicants believe that Schwartz does not identically disclose or describe, within the meaning of 102, the claimed invention.

The Examiner alleges at page 4 of the Office Action that Schwartz teaches a complex that comprises an oligonucleotide in conjunction with an immunostimulatory peptide or antigen; that a complex can comprise an encapsulating agent; that oligonucleotides comprise phosphorothioate backbones; and that an oligonucleotide can be combined with facilitators, which may be linked to the ISS. Applicants fail to see how such teachings in Schwartz specifically disclose or describe the presently claimed invention. Schwartz does not explicitly describe a complex comprising a polynucleotide covalently linked to the surface of a biodegradable micro carrier (MC), wherein the polynucleotide comprises the sequence 5'-CG-3', wherein the polynucleotide is greater than 6 nucleotides in length and wherein said MC is less than 10  $\mu\text{m}$  in size. At page 6 of the Office Action, the Examiner alleges that Schwartz teaches that a microcarrier is less than 10 $\mu\text{m}$ . Applicants invite the Examiner's attention to page 15, lines 36-38 which state that the invention provides compositions and methods that comprise an encapsulating agent. Continuing on page 16, lines 1-3 state that the microparticles and/or liposomes encapsulating an ISS-IMM are in the form of particles with the recited sizes. The presently claimed invention recites, in part, that the polynucleotide is covalently linked to the surface of a biodegradable MC that is less than 10  $\mu\text{m}$  in size.

Further, Applicants respectfully submit that the claimed complex, that is, a complex comprising a polynucleotide covalently linked to the surface of a biodegradable micro carrier (MC), wherein said polynucleotide comprises the sequence 5'-CG-3', wherein the polynucleotide is greater than 6 nucleotides in length and wherein said MC is less than 10  $\mu\text{m}$  in size, does not necessarily flow from Schwartz's general teachings. Thus, Schwartz does not, as a matter of law, explicitly or inherently anticipate the claimed invention.

The Examiner's suggestion that the burden is upon Applicants to show a distinction between the claimed invention and Schwartz is obviated by the fact that Schwartz cannot as a matter of law anticipate the claimed invention.

II. Claims 1-23, 48-84 are rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Carson et al. (WO 98/16247), Ray (WO 99/11275) or Schwartz. Applicants believe the Examiner intended to refer to WO 99/11275 by the correct inventor name "Raz". Applicants respectfully traverse this rejection.

Applicants have addressed Schwartz above. Applicants reiterate those arguments here. While Schwartz may disclose general combinations, the claimed compositions, methods and kits are not explicitly or inherently disclosed in Schwartz. Therefore, Schwartz can not as a matter of law anticipate the claimed invention.

Similarly, while Carson et al. provide disclosure of various ISS combinations, they do not specifically disclose or describe the claimed invention. Carson et al. have no specific disclosure or description of a immunomodulatory polynucleotide/ microcarrier (IMP/MC) complex, comprising, a polynucleotide covalently linked to the surface of a biodegradable micro carrier (MC), wherein said polynucleotide comprises the sequence 5'-CG-3', wherein the polynucleotide is greater than 6 nucleotides in length and wherein said MC is less than 10  $\mu\text{m}$  in size; kits comprising such complexes or methods of using them. Carson et al. do not explicitly describe a polynucleotide comprising the sequence 5'-CG-3' of greater than 6 nucleotides in length covalently linked to the surface of a biodegradable microcarrier that is less than 10  $\mu\text{m}$  in size. Therefore, Carson can not as a matter of law anticipate the claimed invention.

Raz has no specific disclosure or description of a immunomodulatory polynucleotide/ microcarrier (IMP/MC) complex, comprising, a polynucleotide covalently linked to the surface of a biodegradable micro carrier (MC), wherein said polynucleotide comprises the sequence 5'-CG-3', wherein the polynucleotide is greater than 6 nucleotides in length and wherein said MC is less than 10  $\mu\text{m}$  in size; kits comprising such complexes or methods of using them. While Raz states at page

19 that a colloidal dispersion system, including microspheres, may be used, Raz does not explicitly or inherently disclose or describe that the ISS is covalently linked to the surface of a biodegradable microcarrier, wherein said MC is less than 10  $\mu\text{m}$  in size. Further regarding claims 20-21, 66-67, 77-78, and 83-84, Applicants note that Raz at page 2, lines 18-20 state that the ISS-ODN is delivered to the host without co-delivery of an immunizing antigen.

Further, Applicants respectfully submit that the claimed complex, that is, a complex comprising a polynucleotide covalently linked to the surface of a biodegradable micro carrier (MC), wherein said polynucleotide comprises the sequence 5'-CG-3', wherein the polynucleotide is greater than 6 nucleotides in length and wherein said MC is less than 10  $\mu\text{m}$  in size, does not necessarily flow from Schwartz, Carson et al. and Raz general teachings. Therefore Schwartz, Carson et al. and Raz can not as a matter of law anticipate the claimed invention.

Applicants respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. §102.

**CONCLUSION**

Applicants believe that all issues raised in the Office Action have been properly addressed in this response. Accordingly, reconsideration and allowance of the pending claims is respectfully requested. If the Examiner feels that a telephone interview would serve to facilitate resolution of any outstanding issues, the Examiner is encouraged to contact Applicants' representative at the telephone number below.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicants petition for any required relief including extensions of time and authorize the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 377882001420. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

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